

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

WYETH,	)	PUBLIC VERSION
	)	
Plaintiff,	)	C. A. No. 06-222 (JJF)
v.	)	Confidential Version Filed: November 15, 2007
IMPAX LABORATORIES, INC.,	)	Public Version Filed: December 28, 2007
	)	
Defendant.	)	

**DECLARATION OF KAREN JACOBS LOUDEN IN SUPPORT OF  
WYETH'S OPENING BRIEF IN SUPPORT OF ITS  
MOTION TO STRIKE PARAGRAPHS 72-73, 81-84, 129-30 AND  
133-36 OF THE REBUTTAL EXPERT REPORT OF ARTHUR H. KIBBE, Ph.D.**

I, Karen Jacobs Louden, hereby declare as follows:

1. I am a partner with the law firm of Morris, Nichols, Arsh & Tunnell LLP. I am one of the attorneys representing Wyeth in the current litigation.
2. Attached hereto as Exhibit A is a true and correct copy of the Rebuttal Expert Report of Arthur H. Kibbe, Ph.D. dated October 31, 2007.
3. Attached hereto as Exhibit B is a true and correct copy of excerpts from Defendant Impax Laboratories, Inc.'s Responses to Plaintiff's First Set of Interrogatories (Nos. 1-13), dated July 26, 2006.
4. Attached hereto as Exhibit C is a true and correct copy of excerpts from Defendant Impax Laboratories, Inc.'s First Amended Responses to Plaintiff's First Set of Interrogatories (Nos. 1-13), dated October 10, 2006.
5. Attached hereto as Exhibit D is a true and correct copy of excerpts from Defendant Impax Laboratories, Inc.'s Second Amended Responses to Plaintiff's First Set of Interrogatories (Nos. 1-13), dated January 12, 2007.

6. Attached hereto as Exhibit E is a true and correct copy of Wyeth's Proposed Construction of Claim Terms, dated April 13, 2007.

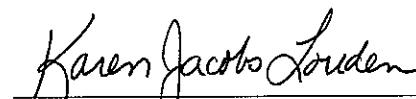
7. Attached hereto as Exhibit F is a true and correct copy of an April 13, 2007 letter from S. Ernst to L. Wadler setting forth Impax's proposed claim constructions.

8. Attached hereto as Exhibit G is a true and correct copy of April 23 and 24, 2007 letters between D. Durie and L. Wadler.

9. Attached hereto as Exhibit H is a true and correct copy of an April 26, 2007 letter from L. Wadler to P. Blizzard.

10. Attached hereto as Exhibit I is a true and correct copy of the Order Resolving Vestar's Motions for Reconsideration in *The Liposome Co., Inc. v. Vestar, Inc.*, Civil Action No. 92-332 (RRM) (D. Del. Nov. 24, 1993).

I declare under penalty of perjury that the foregoing is true and correct, and that this declaration was executed on this 15th day of November, 2007.

  
\_\_\_\_\_  
Karen Jacobs Louden (#2881)

1314127

**CERTIFICATE OF SERVICE**

I, the undersigned, hereby certify that on December 28, 2007, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

Mary B. Matterer  
MORRIS JAMES LLP

I also certify that copies were caused to be served on December 28, 2007 upon the following in the manner indicated:

**BY E-MAIL AND HAND**

Mary B. Matterer  
MORRIS JAMES LLP  
500 Delaware Avenue, Suite 1500  
Wilmington, DE 19899

**BY E-MAIL**

Joseph C. Gratz  
Daralyn J. Durie  
KEKER & VAN NEST LLP  
710 Sansome Street  
San Francisco, CA 94111-1704

*/s/ Karen Jacobs Louden (#2881)*

---

Karen Jacobs Louden (#2881)  
klouden@mnat.com

# EXHIBIT A

FULLY REDACTED

# EXHIBIT B

FULLY REDACTED

# EXHIBIT C

FULLY REDACTED

# EXHIBIT D

FULLY REDACTED

# EXHIBIT E

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

---

WYETH,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C. A. No. 06-222 (JJF)
	)	
IMPAX LABORATORIES, INC.,	)	
	)	
Defendant.	)	
	)	

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**WYETH'S PROPOSED CONSTRUCTION OF CLAIM TERMS**

Wyeth, pursuant to ¶ 8 of the Court's July 13, 2006 Rule 16 Scheduling Order, submits the following construction of terms of the asserted claims of the patents in suit that have been identified by either party as requiring construction. Wyeth reserves the right to modify or supplement its construction because discovery is in progress. Wyeth further reserves the right to modify or supplement its construction to the extent Impax identifies additional claim terms that it considers in dispute.

CLAIM TERM	WYETH'S CONSTRUCTION
with diminished incidence(s) of nausea and emesis	The degree and/or frequency of nausea and emesis from the extended release formulation administered once-a-day is less than what would be experienced by patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day.
extended release formulation	A formulation, other than a hydrogel tablet, which releases the active ingredient at a slower rate than the immediate release formulation of the active ingredient such that the dosing frequency is once-a-day rather than the plural daily dosing for the immediate release formulation.
encapsulated	Filled into a pharmaceutically acceptable capsule.

**CERTIFICATE OF SERVICE**

I, Karen Jacobs Louden, hereby certify that copies of the foregoing were caused to be served this 13th day of April, 2007 upon the following in the manner indicated:

**BY HAND**

Mary B. Matterer  
Morris James LLP  
222 Delaware Avenue  
P.O. Box 2306  
Wilmington, DE 19899

**BY EMAIL**

M. Patricia Thayer  
John M. Benassi  
Jessica R. Wolf  
Heller Ehrman LLP  
4350 La Jolla Village Drive  
San Diego, CA 92102

*/s/ Karen Jacobs Louden*

---

Karen Jacobs Louden (#2881)

# EXHIBIT F

# HellerEhrman LLP

April 13, 2007

*Via E-mail and U.S. Mail*

Samuel F. Ernst  
 Sam.Ernst@HellerEhrman.com  
 Direct +1 (415) 772-6964  
 Direct Fax +1 (415) 772-1759  
 Main +1 (415) 772-6000  
 Fax +1 (415) 772-6268

40443.0005

Linda A. Wadler, Esq.  
 Finnegan, Henderson, Farabow,  
 Garrett & Dunner, L.L.P.  
 901 New York Ave., N.W.  
 Washington, D.C. 20001-4413

**Re: *Wyeth v. Impax Laboratories*, No. 06-222 (D. Del.)**

Dear Linda:

Pursuant to paragraph 8 of the Court's July 13, 2006 Scheduling Order and the parties' agreements with respect to the same as set forth in Ms. Rudolph's letter of today, the following are Impax's proposed claim constructions:

Claim Term	Impax's Proposed Construction
<b>with diminished incidence(s) of nausea and emesis</b>	a decrease in the number of patients suffering from nausea and vomiting compared to patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day
<b>extended release formulation</b>	a formulation comprising venlafaxine, microcrystalline cellulose, and, optionally, HPMC coated with a mixture of ethyl cellulose and HPMC in an amount needed to provide a specific unit dosage administered once-a-day to provide a therapeutic blood plasma level of venlafaxine over the entire 24-hour period of administration
<b>for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride</b>	the peak(s) and trough(s) due to the "therapeutic metabolism" of any second or third dose given in a single day is eliminated by dosing only once every 24 hours
<b>spheroid</b>	one or more particles that are generally shaped like a sphere, although they do not have to be perfectly round

HellerEhrman LLP

Linda Wadler, Esq.  
April 13, 2007  
Page 2

Best regards,

Samuel F. Ernst

cc: Jessica R. Wolff, Esq.  
Daniel N. Kassabian, Esq.  
Eric L. Lane, Esq.  
Daralyn J. Durie, Esq.  
Asim Bhansali, Esq.  
Paula L. Blizzard, Esq.  
Mary B. Matterer, Esq.  
Basil J. Lewris, Esq.  
James K. Hammond, Esq.  
Barbara R. Rudolph, Esq.  
Karen Jacobs Louden, Esq.

# EXHIBIT G

LAW OFFICES  
**KEKER & VAN NEST**  
LLP

710 Sansome Street  
San Francisco, CA 94111-1704  
Telephone (415) 391-5400  
Fax (415) 397-7188  
www.kvn.com

DARALYN J. DURIE  
DDURIE@KVN.COM

April 23, 2007

**VIA EMAIL & U.S. MAIL**

Linda A. Wadler, Esq.  
Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.  
901 New York Avenue, N.W.  
Washington, D.C. 20001

Re: Wyeth v. Impax Laboratories, Inc.

Dear Ms. Wadler:

I write in response to your April 23, 2007 letter to Daniel Kassabian. First, Impax has no additional claim terms to be construed at this time. Second, Impax understands your letter to mean that Wyeth accepts Impax's construction of the term "spheroids," as set forth in Samuel Ernst's April 13, 2007 letter to you. Subject to this understanding, Impax is amenable to indicating to the court that the parties are in agreement on this term.

Very truly yours,

  
Daralyn J. Durie

DJD/jcg

cc: Barbara R. Rudolph, Ph.D., Esq. (via email only)  
Robert A. Pollock, Ph.D., Esq. (via email only)  
Mary B. Matterer, Esq. (via email only)  
Daniel N. Kassabian, Esq. (via email only)



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LINDA A. WADLER

202.408.4037

[linda.wadler@finnegan.com](mailto:linda.wadler@finnegan.com)

April 24, 2007

Daralyn J. Durie, Esq.  
Keker & Van Nest LLP  
710 Sansome Street  
San Francisco, CA 94111

Via E-mail  
Confirmation by U.S. mail

Wyeth v. Impax Laboratories, Inc., Civil Action No.: 06-222 (D. Del.)

Dear Daralyn:

In response to your letter of April 23<sup>rd</sup>, Wyeth believes the parties are in agreement on the construction of the term "spheroid" - the identification of examples is not necessary. Since Impax has not offered an alternative construction to Wyeth's construction of the terms "encapsulated" and "a method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period," we understand that we also can indicate to the Court that the parties are in agreement on those terms as well. If Impax disagrees, please let us know promptly.

Finally, we are not available at 2:00 pm EDT tomorrow for a meet and confer. Would you be available at 5:30 pm EDT/2:30 pm PDT? Please let us know later today.

Sincerely,

A handwritten signature in black ink that appears to read 'Linda'.

Linda A. Wadler

LAW/sas

cc: Mary B. Matterer, Esq. (via e-mail)  
Jessica Wolff, Esq. (via e-mail)  
Daniel Kassabian, Esq. (via e-mail)  
M. Patricia Thayer, Esq. (via e-mail)  
Samuel F. Ernst, Esq. (via e-mail)  
Eric L. Lane, Esq. (via e-mail)  
Karen Jacobs Louden, Esq. (via e-mail)

# EXHIBIT H



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[www.finnegan.com](http://www.finnegan.com)

FINNEGAN  
HENDERSON  
FARABOW  
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DUNNER LLP

LINDA A. WADLER  
202.408.4037  
[linda.wadler@finnegan.com](mailto:linda.wadler@finnegan.com)

April 26, 2007

Paula J. Blizzard, Esq.  
Keker & Van Nest LLP  
710 Sansome Street  
San Francisco, CA 94111

**Via E-mail**  
**Confirmation by U.S. mail**

Wyeth v. Impax Laboratories, Inc., Civil Action No.: 06-222 (D. Del.)

Dear Paula:

I am writing to summarize the parties' positions at the April 25th meet and confer telephone conference regarding claim construction. First, the parties agreed that the only claim terms remaining in dispute are:

- 1) "with diminished incidence(s) of nausea and emesis,"
- 2) "extended release formulation," and
- 3) "A method for eliminating the troughs and peaks of drug concentration in a patients blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride."

Although the parties discussed whether a potential compromise was possible on the claim terms listed above, no compromise was reached. Although Wyeth has considered your comments on the third term listed above, Wyeth intends to maintain the construction of that term as stated in its April 13, 2007 proposed construction of claim terms.

The parties are in agreement on the construction of the terms "spheroid," as reflected in my letter of April 23 to Mr. Kassabian and Impax's April 13, 2007 proposed construction of claim terms. In addition, Impax is agreement with the construction of the terms "encapsulated," and "a method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period" as set forth in Wyeth's April 13, 2007 proposed construction of claim terms.

Although service of the opening Markman briefs via e-mail and hand and service of the exhibits (if too voluminous for e-mail) by next day delivery was discussed, we also

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Paula J. Blizzard, Esq.  
April 26, 2007  
Page 2

agreed that our respective local counsel would be in touch with each other to further discuss and confirm the mechanics of service of the opening Markman briefs.

Sincerely,



Linda A. Wadler

LAW/sas

cc: Mary B. Matterer, Esq. (via e-mail)  
Jessica Wolff, Esq. (via e-mail)  
Daniel Kassabian, Esq. (via e-mail)  
M. Patricia Thayer, Esq. (via e-mail)  
Samuel F. Ernst, Esq. (via e-mail)  
Eric L. Lane, Esq. (via e-mail)  
Karen Jacobs Louden, Esq. (via e-mail)

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

Paula J. Blizzard, Esq.  
April 26, 2007  
Page 3

bcc: Lawrence Alaburda, Esq. (via e-mail)  
Susan Lee, Esq. (via e-mail)  
Jack B. Blumenfeld, Esq. (via e-mail)

# EXHIBIT I

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

FILED

NOV 29 1993

THE LIPOSOME COMPANY, INC., )  
Plaintiff, )  
v. ) Civil Action No. 92-332-RRM  
VESTAR, INC., )  
Defendant. )

TIME \_\_\_\_\_  
CLERK, U.S. DISTRICT COURT  
DISTRICT OF DELAWARE

**ORDER RESOLVING VESTAR'S MOTIONS FOR RECONSIDERATION**

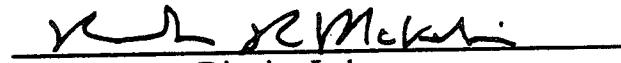
Vestar has moved for reconsideration of two decisions made by the Court during the November 12, 1993 Pretrial Conference. First, it has moved for reconsideration of the Court's decision to preclude it from calling Thomas D. Kiley as an expert witness. Second, it has moved for reconsideration of the Court's decision that plaintiff could assert the doctrine of equivalents as a basis for infringement. The Court having reviewed the additional papers submitted by the parties on these motions,

**IT IS ORDERED AS FOLLOWS:**

1. Vestar's Motion for Reconsideration as to Plaintiff's Motion In Limine to Preclude Defendant's Rebuttal Expert from Testifying (Docket Item 131) Vestar's Motion for reconsideration of the Court's decision to preclude it from calling Thomas D. Kiley to testify as an expert is denied. Vestar failed to identify Mr. Kiley as an expert within the time period provided by the Court in the Scheduling Order in this matter. The deadlines in that Order are consistent with the Court's interest in setting the time for completion of discovery

and ensuring compliance with appropriate requested discovery in a timely fashion. See 28 U.S.C. § 473(a)(2)(C).

2. Vestar's Motion to Exclude from this Case Plaintiff's Claim of Infringement Under the Doctrine of Equivalents (Docket Item 130) Vestar's Motion to preclude Liposome from relying on the doctrine of equivalents is granted. In its Motion, Vestar has shown that during the period for discovery it served an interrogatory on Liposome asking it to state whether its alleged claims were infringed under the doctrine of equivalents. In responding, Liposome did not report that it intended to allege infringement under the doctrine of equivalents. Liposome did not disclose it intended to rely on the doctrine of equivalents until November 7, 1993, after the date for completion of discovery. As Liposome failed to identify this contention in response to Vestar's discovery request, the Court will preclude it from relying on it at trial.

  
\_\_\_\_\_  
United States District Judge

Dated: November 24, 1993